PRV

PATENT- OCH REGISTRERINGSVERKET
Patentavdelningen

Intyg
Certificate

Härmed intygas att bifogade kopior överensstämmer med de handlingar som ursprungligen ingivits till Patent- och registreringsverket i nedannämnda ansökan.

This is to certify that the annexed is a true copy of the documents as originally filed with the Patent- and Registration Office in connection with the following patent application.

PATENT- OCH REGISTRERINGSVERKET • PATENT- AND REGISTRATION OFFICE

(71) *Sökande* / *Applicant* — *St. Jude Medical AB Järfälla SE, Hedberg Sven-Erik Kungsängen SE, Björling Anders Järfälla SE, Holmström Nils Järfälla SE, Lagercrantz Per Stockholm SE,*

(81) *Designerade stater* / *Designated states* — *AP: all, AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LI, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW*

(21) *Patentansökningsnummer* / *Patent application number* — *PCT SE03/01494*

(86) *Ingivningsdatum* / *Date of filing* — *2003-09-25*

Stockholm, 2005-02-10

För Patent- och registreringsverket
For the Patent- and Registration Office

Görel Gustafsson

Avgift
Fee *170:-*

PATENT- OCH REGISTRERINGSVERKET
SWEDEN

Postadress/Adress
Box 5055
S-102 42 STOCKHOLM

Telefon/Phone
+46 8 782 25 00
Vx 08-782 25 00

Telex
17978
PATOREG S

Telefax
+46 8 666 02 86
08-666 02 86

PCT REQUEST

P 03-214

Original (for **SUBMISSION**) - printed on 25.09.2003 09:14:14 AM

0	**For receiving Office use only**	
0-1	International Application No.	PCT/SE 03/01494
0-2	International Filing Date	25-09-2003
0-3	Name of receiving Office and "PCT International Application"	The Swedish Patent Office PCT International Application

0-4	**Form - PCT/RO/101 PCT Request**	
0-4-1	Prepared using	PCT-EASY Version 2.92 (updated 01.07.2003)
0-5	**Petition** The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	**Receiving Office (specified by the applicant)**	Swedish Patent Office (RO/SE)
0-7	**Applicant's or agent's file reference**	P 03-214
I	**Title of invention**	HEART STIMULATION DEVICE
II	**Applicant**	
II-1	This person is:	applicant only
II-2	Applicant for	all designated States except US
II-4	Name	St. Jude Medical AB
II-5	Address:	SE-175 84 JÄRFÄLLA Sweden
II-6	State of nationality	SE
II-7	State of residence	SE
III-1	**Applicant and/or inventor**	
III-1-1	This person is:	applicant and inventor
III-1-2	Applicant for	US only
III-1-4	Name (LAST, First)	HEDBERG, Sven-Erik
III-1-5	Address:	Odonstigen 5 S-196 32 KUNGSÄNGEN Sweden
III-1-6	State of nationality	SE
III-1-7	State of residence	SE

PCT REQUEST

P 03-214

Original (for **SUBMISSION**) - printed on 25.09.2003 09:14:14 AM

III-2	**Applicant and/or inventor**	
III-2-1	This person is:	applicant and inventor
III-2-2	Applicant for	US only
III-2-4	Name (LAST, First)	BJÖRLING, Anders
III-2-5	Address:	Handbollsvägen 24 G S-175 53 JÄRFÄLLA Sweden
III-2-6	State of nationality	SE
III-2-7	State of residence	SE
III-3	**Applicant and/or inventor**	
III-3-1	This person is:	applicant and inventor
III-3-2	Applicant for	US only
III-3-4	Name (LAST, First)	HOLMSTRÖM, Nils
III-3-5	Address:	Päronvägen 4 A S-175 57 JÄRFÄLLA Sweden
III-3-6	State of nationality	SE
III-3-7	State of residence	SE
III-4	**Applicant and/or inventor**	
III-4-1	This person is:	applicant and inventor
III-4-2	Applicant for	US only
III-4-4	Name (LAST, First)	LAGERCRANTZ, Per
III-4-5	Address:	St Paulsgatan 22 B S-118 48 STOCKHOLM Sweden
III-4-6	State of nationality	SE
III-4-7	State of residence	SE
IV-1	**Agent or common representative; or address for correspondence** The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:	agent
IV-1-1	Name (LAST, First)	HOPFGARTEN, Nils
IV-1-2	Address:	Groth & Co. KB P. O. Box 6107 S-102 32 Stockholm Sweden
IV-1-3	Telephone No.	+46 8 729 91 00
IV-1-4	Facsimile No.	+46 8 31 67 67
IV-1-5	e-mail	info@groth.se

PCT REQUEST

P 03-214

Original (for SUBMISSION) - printed on 25.09.2003 09:14:14 AM

IV-2	Additional agent(s)	additional agent(s) with same address as first named agent
IV-2-1	Name(s)	KARLSSON, Leif; AXELSSON, Nils Åke; ASKERBERG, Fredrik; EMTEDAL, Artur; JOHANSSON, WEBJÖRN, Ingmari; KÄRN, Ulf; LINDBLOM, Erik, J.; THEANDER, Anna
V	Designation of States	
V-1	Regional Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	AP: GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW and any other State which is a Contracting State of the Harare Protocol and of the PCT (patent and utility model) EA: AM AZ BY KG KZ MD RU TJ TM and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT EP: AT BE BG CH&LI CY CZ DE DK EE ES FI FR GB GR HU IE IT LU MC NL PT RO SE SI SK TR and any other State which is a Contracting State of the European Patent Convention and of the PCT OA: BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG and any other State which is a member State of OAPI and a Contracting State of the PCT

PCT REQUEST

P 03-214

Original (for SUBMISSION) - printed on 25.09.2003 09:14:14 AM

V-2	National Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	AE ~~[(utility model)]~~ AG AL ~~[(utility model)]~~ AM ~~[(utility model)]~~ AT (utility model) AU AZ ~~[(utility model)]~~ BA BB BG ~~[(utility model)]~~ BR ~~[(utility model)]~~ BY ~~[(utility model)]~~ BZ ~~[(utility model)]~~ CA CH&LI CN ~~[(utility model)]~~ CO ~~[(utility model)]~~ CR ~~[(utility model)]~~ CU CZ (utility model) DE (utility model) DK (utility model) DM DZ EC ~~[(utility model)]~~ EE (utility model) EG ES ~~[(utility model)]~~ FI (utility model) GB GD GE GH GM HR HU ~~[(utility model)]~~ ID IL IN IS JP ~~[(utility model)]~~ KE ~~[(utility model)]~~ KG KP ~~[(utility model)]~~ KR ~~[(utility model)]~~ KZ LC LK LR LS ~~[(utility model)]~~ LT LU LV MA MD ~~[(utility model)]~~ MG MK MN MW MX ~~[(utility model)]~~ MZ ~~[(utility model)]~~ NI NO NZ OM PG PH ~~[(utility model)]~~ PL ~~[(utility model)]~~ PT ~~[(utility model)]~~ RO RU ~~[(utility model)]~~ SC SD SE SG SK (utility model) SL ~~[(utility model)]~~ SY TJ ~~[(utility model)]~~ TM TN TR ~~[(utility model)]~~ TT TZ UA ~~[(utility model)]~~ UG US UZ ~~[(utility model)]~~ VC VN YU ZA ZM ZW
V-5	**Precautionary Designation Statement** In addition to the designations made under items V-1, V-2 and V-3, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except any designation(s) of the State(s) indicated under item V-6 below. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit.	
V-6	**Exclusion(s) from precautionary designations**	NONE
VI	**Priority claim**	NONE
VII-1	**International Searching Authority Chosen**	Swedish Patent Office (ISA/SE)

PCT REQUEST

P 03-214

Original (for **SUBMISSION**) - printed on 25.09.2003 09:14:14 AM

VIII	Declarations	Number of declarations	
VIII-1	Declaration as to the identity of the inventor	–	
VIII-2	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	–	
VIII-3	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	–	
VIII-4	Declaration of inventorship (only for the purposes of the designation of the United States of America)	–	
VIII-5	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	–	
IX	**Check list**	number of sheets	electronic file(s) attached
IX-1	Request (including declaration sheets)	6 ✓	–
IX-2	Description	5 ✓	–
IX-3	Claims	1 ✓	–
IX-4	Abstract	1 ✓	EZABST00.TXT
IX-5	Drawings	5 ✓	–
IX-7	TOTAL	18 ✓	
	Accompanying items	paper document(s) attached	electronic file(s) attached
IX-8	Fee calculation sheet	✓	–
IX-17	PCT-EASY diskette	–	Diskette
IX-19	**Figure of the drawings which should accompany the abstract**	5	
IX-20	**Language of filing of the international application**	English	
X-1	**Signature of applicant, agent or common representative**	Nils Hopfgarten	
X-1-1	Name (LAST, First)	HOPFGARTEN, Nils	

FOR RECEIVING OFFICE USE ONLY

10-1	Date of actual receipt of the purported international application	25-09-2003
10-2	Drawings:	
10-2-1	Received X	
10-2-2	Not received	
10-3	Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application	
10-4	Date of timely receipt of the required corrections under PCT Article 11(2)	
10-5	International Searching Authority	ISA/SE
10-6	Transmittal of search copy delayed until search fee is paid	

PCT REQUEST

P 03-214

Original (for SUBMISSION) - printed on 25.09.2003 09:14:14 AM

FOR INTERNATIONAL BUREAU USE ONLY

11-1	Date of receipt of the record copy by the International Bureau	

ABSTRACT

A biventricular stimulation device comprises a pulse generator for delivering stimulation pulses at least to the ventricles of a patient's heart. An evoked response detector has first and second, independent ventricular sensing channels for ventricular evoked response detection in the ventricles. The pulse generator is controlled to deliver stimulation pulses (106) to the second ventricle (RV) with a VV time delay after stimulation pulse delivery (104) to the first stimulated ventricle (LV) which is shorter than an evoked response detection time window (106) following the delivery of the stimulation pulse (104) to the first ventricle. The evoked response detector is arranged to close the evoked response detection time window (106) or discard detections therein in response to the emission of a stimulation pulse (107) to the second ventricle (RV) during the evoked response detection time window (106) of the first stimulated ventricle (LV).

(Fig. 5)

PCT/SE 03/01494

HEART STIMULATION DEVICE

Technical field

The present invention relates to a biventricular stimulation device comprising a pulse generator for delivering stimulation pulses at least to the ventricles of a patient's heart, and an evoked response detector having first and second, independent ventricular sensing channels for ventricular evoked response detection in the ventricles, said pulse generator being controlled to deliver said stimulation pulses to the second ventricle with a VV time delay after stimulation pulse delivery to the first stimulated ventricle which is shorter than an evoked response detection time window following delivery of a stimulation pulse to the first stimulated ventricle.

Background

In the following the ventricle set to be stimulated first is referred to as "the first ventricle", and the ventricle that is set to be stimulated second as "the second ventricle". Even though there is a difference both in stimulation threshold and amplitude of intrinsic signals for the left and the right ventricles, there will be no difference in stimulation strategy if the left or right ventricle is stimulated first. The terms "first" and "second" are only related to the programming of the stimulation device.

In a biventricular pacemaker with a comparatively short VV time delay of less than e.g. 40 msec the evoked response time window, ERW, for the first stimulated ventricle will be interrupted by a stimulation pulse delivered to the second ventricle, i.e. the last stimulated ventricle of the heart. Thus beat-to-beat evoked response, ER, detection on the first ventricle is impossible with such a short VV time delay.

However, in some cases ER detection is possible on the first ventricle regardless of a short VV time delay as mentioned above.

The purpose of the present invention is to utilize this possibility for providing a biventricular stimulation device with an improved possibility to ER detection in the first ventricle despite a short VV time delay.

Disclosure of the invention

This purpose is obtained by a biventricular stimulation device of the kind defined in the introductory portion and having the characterizing features of claim 1.

For a normal stimulation pattern in biventricular stimulation devices the left ventricle is the first stimulated heart chamber and the right ventricle the second one, since LBBB is much more frequent than RBBB. An intrinsic R wave originating from e.g. a conducted P wave will thus be sensed in the right ventricle, probably shortly after the stimulation pulse is delivered to the left ventricle. In the stimulation device according to the invention an ERW is always started after each one of the stimulation pulses to the first ventricle even when a short VV time delays is programmed. The evoked response detector of the stimulation device is then arranged to close the ERW or discard detections therein in response to the emission of a stimulation pulse to the second ventricle during the ERW of the first stimulated ventricle. Thus, only if there is emitted a stimulation pulse to the second ventricle no decision concerning capture or loss of capture of the first ventricle will be taken. An important feature of the stimulation device according to the invention is that the evoked response detector is provided with first and second, independent ventricular sensing channels for ventricular evoked response detection in the respective ventricles, as in for instance Epic HF.

According to advantageous embodiments of the device according to the invention an inhibiting means is provided for inhibiting stimulation in the second ventricle in response to the detection of a sensed intrinsic cardiac event therein, and the VV time delay is less than 40 msec, preferably in the range of 10-30 msec, and the duration of ERW is in the range of 40-100 msec.

Brief description of the drawings

To further explain the invention an embodiment of the device according to the invention will be described in greater detail with reference to the accompanying drawings on which figure 1 illustrates typical placements in the heart of the leads of a stimulation device according to the invention having also an atrial lead implanted, figure 2 is a block diagram of the main electronic circuitry units of a stimulation device like the pacemaker shown in figure 1, figure 3 is a block diagram illustrating the input/output stage in figure 2 in greater detail, figure 4 is a

flow diagram illustrating the function of the embodiment described in connection with the preceding figures, and figure 5 is a timing diagram further illustrating the function of the described embodiment of the device according to the invention.

Description of a preferred embodiment

Figure 1 shows a heart stimulation device in the form of a pacemaker 10 having an atrial 20 and two ventricular leads 24, 30 for stimulating and independently sensing in the left atrium and the ventricles of the heart 12. The figure shows typical positions for an atrial electrode 22, right ventricular electrodes 32, 34 and a left ventricular electrode 26 placed in the coronary sinus. The biventricular pacing lead configuration comprises an unipolär left ventricular lead 24, 26 and a bipolar right ventricular lead 30, 32, 34. By implanting an atrial lead 20, 22 AV synchronous pacing modes are also possible.

Figure 2 is an electronic circuitry block diagram of the main units of the pacemaker 10 in figure 1. The implanted leads 20, 24, 30 in figure are connected to an input/output stage 40 in the pacemaker 10. The stage 40 comprises a pacing and a sensing module as will be further described in connection with figure 3. The operation on the pacemaker is controlled by a CPU 42. The pacemaker also includes a memory for storing information about e.g. how the stimulation threshold has changed over time, how much stimulation has been given, energy consumption etc. which is read out at follow ups. Telemetry means 46 are provided for the communication between the implanted pacemaker and an external programmer.

The input/output stage 40 to which the leads 20, 24 and 30 are connected is shown in a larger scale in figure 3. Thus this stage 40 comprises three channels, one lead 20, 24, and 30 respectively being connected to each of the channels. Each channel comprises a pacing module and a sensing module, and each pacing module includes a pacing stage 48, 50, 52 connected to an amplifier 54, 56, 58. The leads 20, 24, 30 are connected to the outputs of the amplifiers 54, 56, 58 for delivering stimulation pulses to the patient's heart as controlled from the CPU 42.

The leads 20, 24, 30 are also used for sensing signals in the heart and can be connected, via switches 60, 62, 64 to the sensing module of each channel. Each sensing module includes an amplifier 66, 68, 70 in which sensed signals are amplified and the amplified signals are then supplied to an event detector 72, 74, 76 and ER detector 78, 80, 82 for detecting possible evoked response of the heart.

It is important that the three channels for stimulation and sensing are separated.

The switches 60, 62, 64 are controlled to disconnect all sensing modules whenever a stimulation pulse is delivered on anyone of the channels to avoid that the stimulation give rise to disturbances and saturation in the sensing modules. The switches 60, 62, 64 are controlled to otherwise connect the sensing modules to their respective lead 20, 24, 30.

The CPU 42 comprises an inhibiting means for inhibiting stimulation in the second ventricle, e.g. the right ventricle, in response to the detection by the associated sensing module of a sensed cardiac event therein within the VV time delay. The evoked response detector is arranged to close the evoked response detection time window of the first ventricle or discard detections therein in response to the emission of a stimulation pulse to the second ventricle, during the evoked response detection time window of the first stimulated ventricle.

The operation of the above embodiment of the stimulation device according to the invention is illustrated by a flow diagram in figure 4. Thus a command is given triggering stimulation of the first ventricle V1. Collection of data for evoked response, ER, detection in the first ventricle is started, block 84. If no cardiac event, like an R wave, R2, is detected in the second ventricle within the predetermined VV time delay, blocks 86 and 88, a stimulation pulse is delivered to the second ventricle V2, block 90. The connection of ER 1 data is then aborted, block 92, and possible resulting evoked response ER 2 is evaluated and the main procedure is continued.

If a cardiac event in the second ventricle, R2, is detected before the expire of the VV time delay stimulation to the second ventricle, V2, is inhibited by the inhibiting means, block 94. If the collection of evoked response data ER1 from the first ventricle is then completed, block 96, these data are evaluated for detection of possible evoked response, block 98, otherwise this ER1 data collection is repeated or continued till completion, cf. block 96. After terminated evoked response detection in the first ventricle the main procedure is repeated.

An example of the operation of the device according to the invention is also illustrated by a timing diagram in figure 5. Line A relates to the atrium and lines LV and RV to the left and right ventricles respectively. P-waves are shown at 100, 102. The left ventricle LV is first stimulated at 104 and an evoked response detection time window ERW is following this stimulation pulse 104. If a stimulation

pulse 107 is delivered to the second ventricle RV the ERW of the first ventricle 106 will be closed and the results discarded. No decision concerning capture or loss of capture will then be taken.

The stimulation pulse 107 to the right second ventricle is followed by an ERW 108 for detection of capture or loss of capture in normal way.

If an intrinsic R wave 110 is detected in the second ventricle RV, e.g. originating from a conducted P wave 102, this intrinsic R wave 110 will be sensed in the second ventricle RV, probably shortly after the stimulation pulse in the first ventricle LV. The sensed R wave 110 in the second ventricle RV will then control the inhibiting means to inhibit the second stimulation pulse and ER detection in the associated ERW 112 of the first ventricle LV is performed. Thus, to sum up, if a RV stimulation pulse is emitted during the LV evoked response detection time window no ER detection is performed in LV, else ER detection will always be performed in LV.

The example above relates to patients for which the LV stimulation is programmed to come first, e.g. most LBBB patients. For most RBBB patients the situation will be analogous with first and second ventricles shifted

PCT/SE 03/01494

CLAIMS

1. A biventricular stimulation device comprising a pulse generator for delivering stimulation pulses at least to the ventricles of a patient's heart, and an evoked response detector having independent, first and second ventricular sensing channels for ventricular evoked response detection in the ventricles, said pulse generator being controlled to deliver said stimulation pulses to the second ventricle with a VV time delay after stimulation pulse delivery to the first stimulated ventricle which is shorter than an evoked response detection time window following delivery of a stimulation pulse to the first stimulated ventricle, **characterized** in that said evoked response detector is arranged to close said evoked response detection time window or discard detections therein in response to the emission of a stimulation pulse to the second ventricle during said evoked response detection time window of the first stimulated ventricle.

2. The device according to claim 1, **characterized in** that an inhibiting means is provided for inhibiting stimulation in the second ventricle in response to the detection of a sensed intrinsic cardiac event therein.

3. The device according to claim 1 or 2, **characterized in** that said VV time delay is less than 40 msec, preferably in the range of 10 – 30 msec.

4. The device according to any of the preceding claims, **characterized in** that the duration of said evoked response detection time window is in the range of 40 – 100 msec.

PCT/SE 03/01494

ABSTRACT

A biventricular stimulation device comprises a pulse generator for delivering stimulation pulses at least to the ventricles of a patient's heart. An evoked response detector has first and second, independent ventricular sensing channels for ventricular evoked response detection in the ventricles. The pulse generator is controlled to deliver stimulation pulses (106) to the second ventricle (RV) with a VV time delay after stimulation pulse delivery (104) to the first stimulated ventricle (LV) which is shorter than an evoked response detection time window (106) following the delivery of the stimulation pulse (104) to the first ventricle. The evoked response detector is arranged to close the evoked response detection time window (106) or discard detections therein in response to the emission of a stimulation pulse (107) to the second ventricle (RV) during the evoked response detection time window (106) of the first stimulated ventricle (LV).

(Fig. 5)

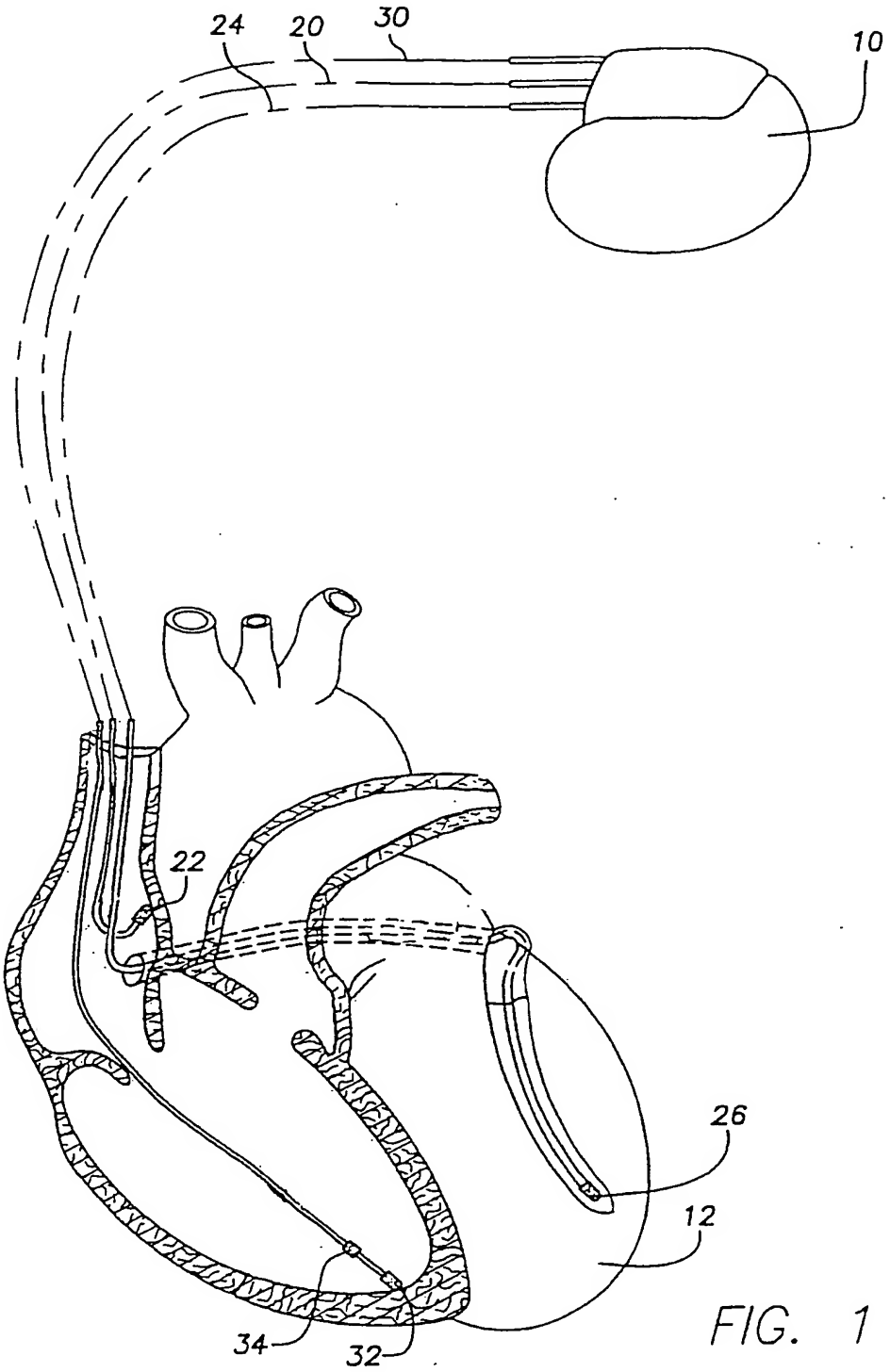

FIG. 1

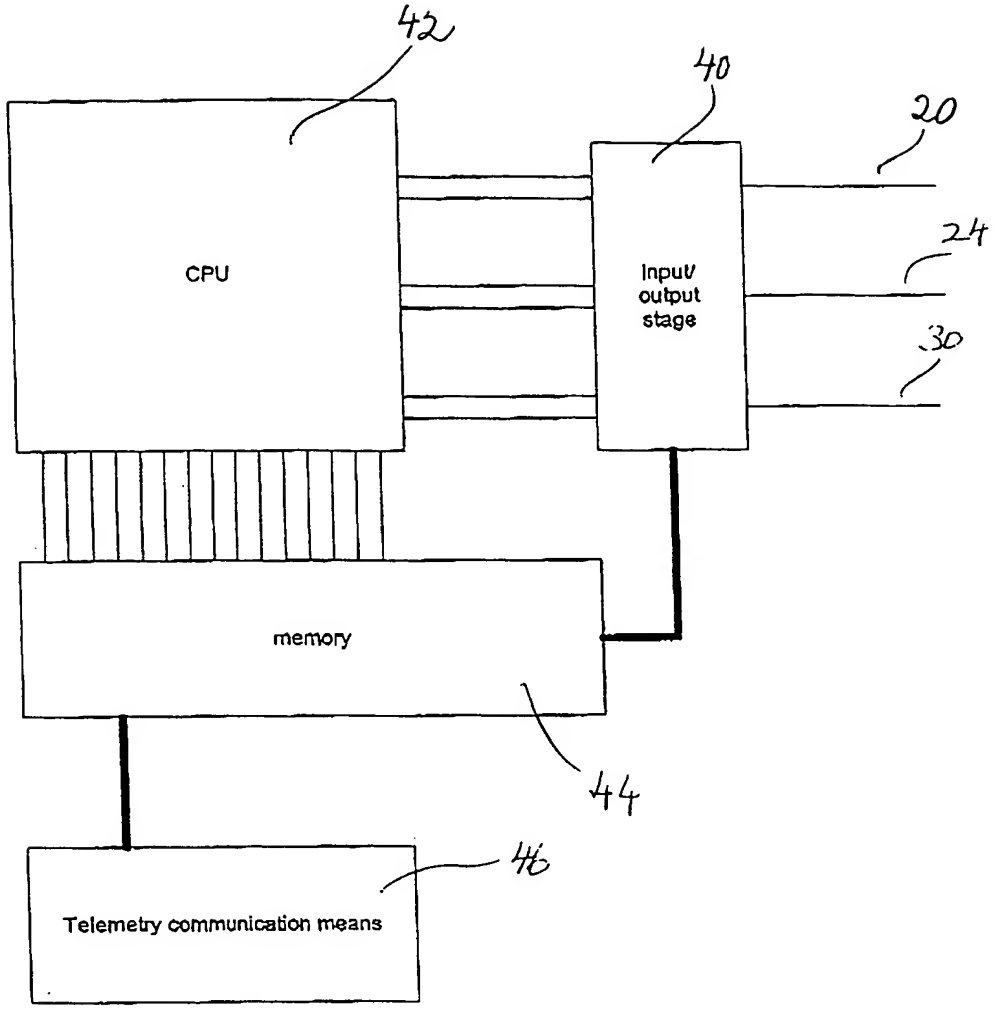
42
40
20
24
30
CPU
Input/
output
stage
memory
44
46
Telemetry communication means

Fig. 2

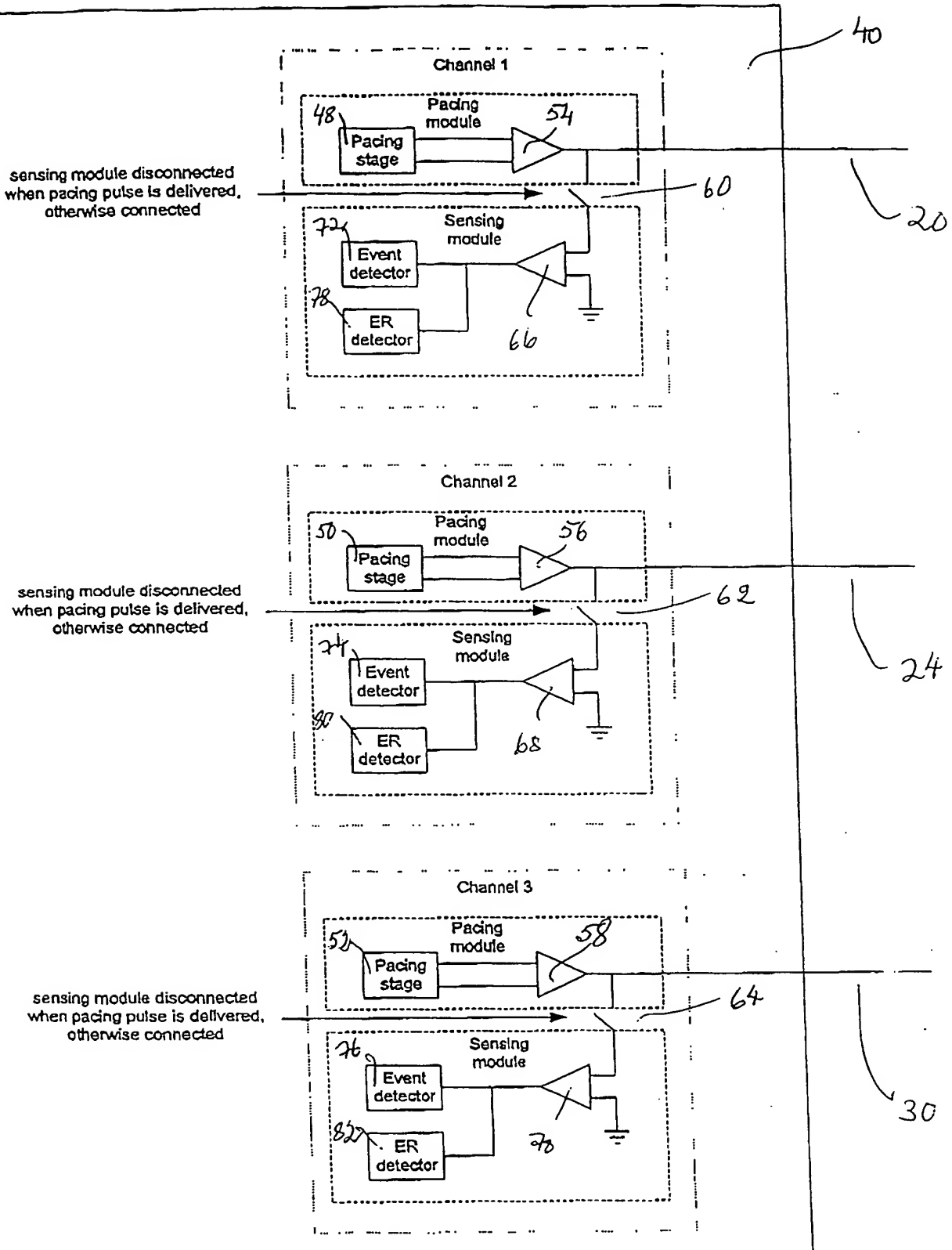
40
Channel 1
48
Pacing module
Pacing stage
54
sensing module disconnected when pacing pulse is delivered, otherwise connected
60
20
72
Sensing module
Event detector
78
ER detector
66
Channel 2
50
Pacing module
Pacing stage
56
sensing module disconnected when pacing pulse is delivered, otherwise connected
62
24
74
Sensing module
Event detector
80
ER detector
68
Channel 3
52
Pacing module
Pacing stage
58
sensing module disconnected when pacing pulse is delivered, otherwise connected
64
30
76
Sensing module
Event detector
82
ER detector
70

Fig. 3

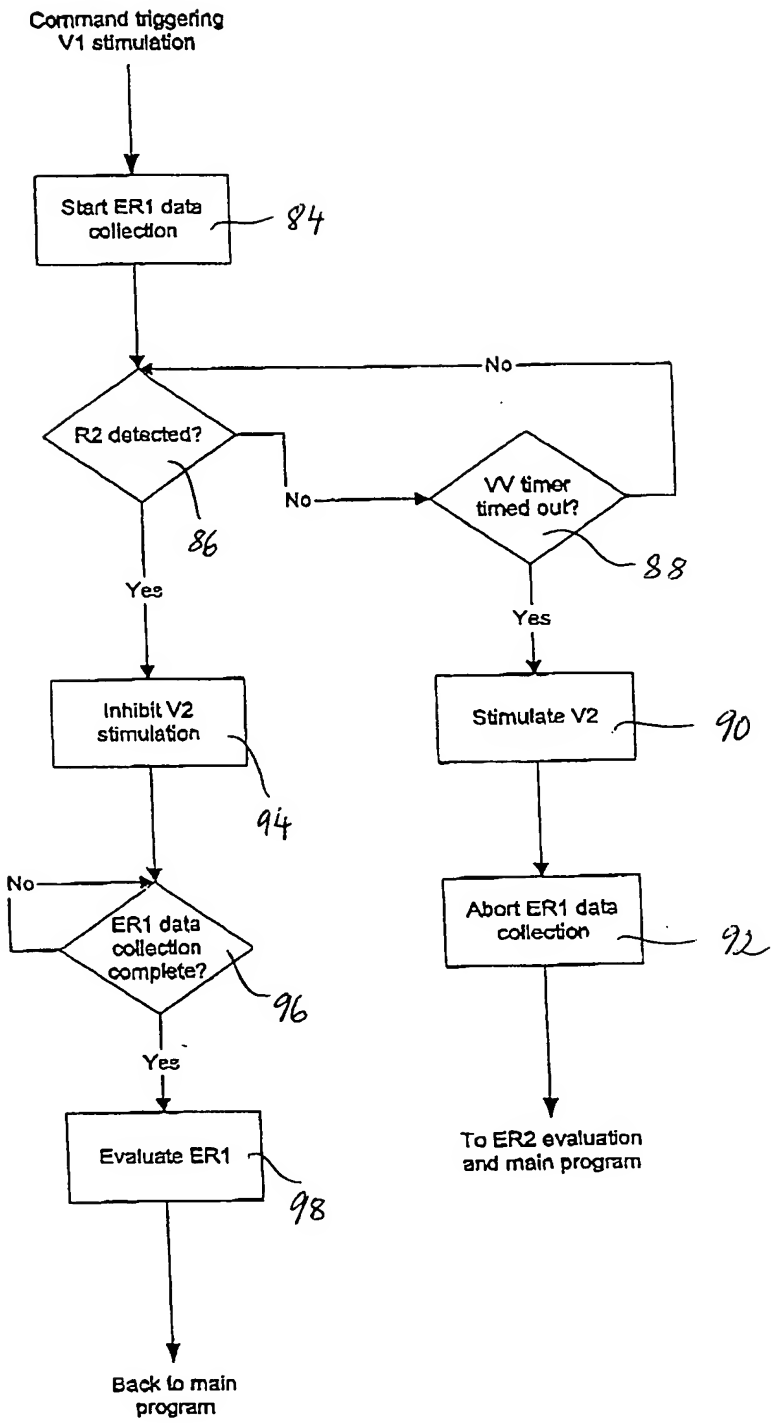
Command triggering V1 stimulation
Start ER1 data collection
84
R2 detected?
86
No
No
VV timer timed out?
88
Yes
Yes
Inhibit V2 stimulation
94
Stimulate V2
90
No
ER1 data collection complete?
96
Abort ER1 data collection
92
Yes
Evaluate ER1
98
To ER2 evaluation and main program
Back to main program

Fig. 4

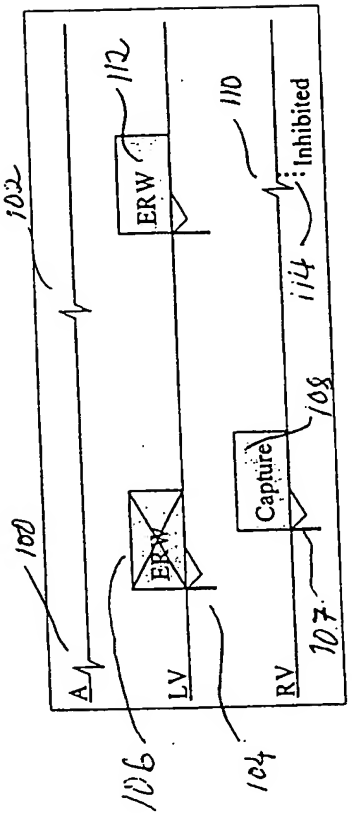
A
LV
RV
ERW
ERW
Capture
Inhibited
100
102
104
106
107
108
110
112
114

Fig. 5